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Case No.: 57666US005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	SLOWEY, ALEXANDER D.		
Application No.:	10/509184	Confirmation No.:	7403
Filed:	March 21, 2003	Group Art Unit	1616
Title:	FORMOTEROL AND MOMETASONE AEROSOL FORMULATIONS		

BRIEF ON APPEAL

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3-17-2008 Shelley M Conoryea

Date Signed by: Shelley M. Conoryea

Dear Sir:

This is an appeal from the Office Action mailed on October 16, 2007.

Fees

☒ Any required fee under 37 CFR § 41.20(b)(2) will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees under 37 CFR § 1.17 which may be required to Deposit Account No. 13-3723.

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A Notice of Appeal in this application was mailed on January 16, 2008, and was received in the USPTO on January 16, 2008.

Appellants request the opportunity for a personal appearance before the Board of Appeals to argue the issues of this appeal. The fee for the personal appearance will be timely paid upon

Appellants request the opportunity for a personal appearance before the Board of Appeals to argue the issues of this appeal. The fee for the personal appearance will be timely paid upon receipt of the Examiner's Answer.

REAL PARTY IN INTEREST

The real party in interest is 3M Company (formerly known as Minnesota Mining and Manufacturing Company) of St. Paul, Minnesota and its affiliate 3M Innovative Properties Company of St. Paul, Minnesota.

RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any related appeals or interferences.

STATUS OF CLAIMS

Claims 1-14 and 17 are pending. Claims 15 and 16 have been canceled. Claims 1-14 and 17 stand rejected.

STATUS OF AMENDMENTS

No amendments have been filed after the final rejection.

SUMMARY OF CLAIMED SUBJECT MATTER

The claimed invention is for a pharmaceutical aerosol dispenser containing a particular two-drug combination—formoterol and mometasone, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative of either—dispersed in propellants HFC 134a and/or 227, along with a sub-micron bulking agent (see claim 1 and page 3, first paragraph of specification), and wherein the interior of the aerosol vial is coated with a fluorocarbon polymer (p. 10, lines 27-30).

The use of a nano-sized bulking agent provides a formulation of both drugs in suspension having high physical stability and homogeneity (p. 3, lines 5-7), and aids in minimizing the tendency of both drugs to cream or sediment, independent of the denisity difference of the drugs to one another and to the propellant (p. 3, lines 16-20).

The use of a sub-micron bulking agent is disclosed in commonly assigned application PCT US01/30575 (page 3, lines 26-29), but not in a formulation of formoterol and mometasone.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

First Ground of Rejection

Claims 1-14 and 17 stand rejected under 35 USC § 112, second paragraph, as purportedly indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

Second Ground of Rejection

Claims 1-14 and 17 stand rejected under 35 USC § 103(a) as purportedly unpatentable over Trofast et al. (WO 00/53187) in view of Ashurst et al. (US 6,131,566).

ARGUMENT

First Ground of Rejection

The rejection of claims 1-14 and 17 under 35 USC § 112, second paragraph, is based on the allegedly indefinite use of the term "derivatives" in claim 1. The final Office Action of 10/16/2007 states that based on the definition in Webster's Dictionary the term derivative is unclear.

Applicants respectfully submit that in view of the definition and description of formoterol and mometasone derivatives given at page 4, line 30, to page 5, line 2, the term would be easily understood by one of ordinary skill in the art (emphasis added):

> By the term "physiologically functional derivatives" is meant a chemical derivative of formoterol or mometasone having the same physiological function as the free compound, for example, by being convertible in the body thereto. According to the present invention, examples of physiologically functional derivatives includes esters.

Webster's Dictionary definition is not the proper standard for determining definiteness when Applicants have given clear guidance in the disclosure. In the context of the present claims and disclosure the term "derivatives" is clear and Applicants therefore request that this rejection be reversed.

Second Ground of Rejection

Claims 1-14 and 17 stand rejected under 35 USC § 103(a) as purportedly unpatentable over Trofast et al. (WO 00/53187) in view of Ashurst et al. (US 6,131,566).

Trofast et al. discloses combinations of formoterol and mometasone in various aerosol formulations, such as nebulizers, dry powder inhalers (DPIs), and pressurized metered dose inhalers (MDIs). There are examples of DPI formulations (see examples 1-6 on pages 7-8) and propellant based MDI formulations with HFC 134a and/or 227 (see examples 7 and 8 on page 8).

Trofast et al. also discloses use of a "diluent or carrier" such as lactose, dextran, mannitol or glucose (p. 5, lines 27-28), and a key question is whether such disclosure relates only to the DPI formulations or is also applicable to the MDI formulations. The Examiner has asserted that the disclosure of this diluent or carrier constitutes a disclosure of bulking agent in an MDI formulation as required by the present claims. Moreover, the Examiner has asserted that the teaching at page 6, lines 9-11, regarding particle sizes of "less than 10" microns constitutes disclosure of a submicron bulking agent in an MDI formulation.

The Examiner cites Ashurst et al. for its disclosure regarding fluoropolymer-coated canisters as called for by the claims.

Applicants respectfully disagree with, *inter alia,* the Examiner's reliance on Trofast et al. because (a) the "diluent or carrier" appears to be directed to the context of a DPI formulation and not as an MDI bulking agent, and (b) the reference to particle size less than 10 microns (besides not being a meaningful disclosure of less than 1 micron) is expressly talking about the "active ingredients" and thus not the diluent or carrier.

Regarding the first point, a careful reading of Trofast et al. from page 5, line 24, to page 6, line 20, shows that the diluent or carrier is generally in the context of "powder" formulations. There is no meaningful link to MDI formulations and the separate full paragraph (page 6, lines 13-20) focusing on MDI formulations does not mention diluent or carrier. This understanding is reinforced by the last sentence of page 6, referring to the "dry powder formulation containing an additive, diluent or carrier" followed by examples where three of them, Ex. 4-6, include lactose but no propellant (and are clearly DPI formulations), whereas the two examples 7 and 8 with propellant do not have lactose or any other bulking agent.

Regarding the second point, not only is the Trofast et al. reference to "less than 10" microns inapplicable because it is 10 times the maximum size range called for the present claims.

it is explicitly referring to the "active ingredient." The diluent or carrier, even if one believes could refer to a MDI formulation bulking agent, is clearly not considered an active ingredient, so the less than 10 micron size disclosure is inapplicable.

Accordingly, it is submitted that the Examiner has not established a *prima facie* case of obviousness and Applicants therefore request that this rejection be reversed.

CONCLUSION

For the foregoing reasons, appellants respectfully submit that the Examiner has erred in rejecting this application. Please reverse the Examiner on all counts.

Respectfully submitted,

March 17, 2008
Date

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Office of Intellectual Property Counsel
3M Innovative Properties Company
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CLAIMS APPENDIX

Listing of Claims

1. (Previously presented) A dispenser comprising an aerosol vial equipped with a dispensing valve, said aerosol vial containing a pharmaceutical aerosol formulation comprising particles of (a) formoterol or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof and (b) mometasone or a pharmaceutically acceptable salt, solvate, or physiologically functional derivative thereof dispersed in a propellant selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane and a mixture thereof, and a bulking agent having a mass median diameter of less than one micron, and wherein an interior surface of the aerosol vial is coated with a fluorocarbon polymer.
2. (Original) A pharmaceutical aerosol formulation according to claim 1, wherein the formoterol is in the form of formoterol fumarate.
3. (Original) A pharmaceutical aerosol formulation according to claim 2, wherein the formoterol is in the form of formoterol fumarate dihydrate.
4. (Previously presented) A pharmaceutical aerosol formulation of claim 1, wherein the mometasone is in the form of mometasone furoate.
5. (Previously presented) A pharmaceutical aerosol formulation according to claim 1, wherein the formoterol is present in an amount of about 0.06 to 0.60 mg per ml.
6. (Previously presented) A pharmaceutical aerosol formulation according to claim 1, wherein the mometasone is present in amount of about 0.5 to 15.0 mg per ml.
7. (Previously presented) A pharmaceutical aerosol formulation according to claim 1, wherein the bulking agent is selected from groups consisting of ascorbic acid, saccharides, polysaccharides, amino acids, organic and inorganic salts, urea and propyliodone.
8. (Original) A pharmaceutical aerosol formulation according to claim 7, wherein the bulking agent is selected from lactose, DL-alanine, glucose, D-galactose, D(+)trehalose dihydrate, sucrose, maltose, D(+)raffinose pentahydrate, sodium saccharin, starches, modified celluloses, dextrins, dextrans, glycine, sodium chloride, calcium carbonate, sodium tartrate and calcium lactate.

9. (Previously presented) A pharmaceutical aerosol formulation according to claim 7, wherein the bulking agent is lactose.
10. (Previously presented) A pharmaceutical aerosol formulation according to claim 1, wherein the weight ratio of formoterol to bulking agent is in the range 1:0.1 to 1:30.
11. (Previously presented) A pharmaceutical aerosol formulation according to claim 1, wherein the bulking agent has a mass median diameter of not more than 300 nm.
12. (Previously presented) A pharmaceutical aerosol formulation according to claim 1, wherein the formulation further comprises a surfactant.
13. (Previously presented) A pharmaceutical aerosol formulation according to claim 1, wherein the formulation further comprises ethanol.
14. (Original) A pharmaceutical aerosol formulation according to claim 13, wherein ethanol is present in amount of from 0.1 to 5% by weight of the formulation.
15. (Cancelled)
16. (Cancelled)
17. (Original) A method of preparing a formulation according to claim 1, the method comprising the steps of (i) forming a slurry of bulking agent with a component of the formulation; (ii) subjecting the slurry to high pressure homogenization; and (iii) combining the resulting slurry with other components of the aerosol formulation.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.